9.0 PREMARKET NOTIFICATION 510(K) SUMMARY

Applicant:	Jerald P. Steiner, Ph.D. Fisher Diagnostics 8365 Valley Pike P.O. Box 307 Middletown, VA 22645-0307 (540) 868-3200
Contact Person:	Nadia Greenidge (same address and phone number)
Date:	September 5, 2001
Trade Name:	INR Control Plasmas
Common Name:	INR Control Plasmas
Classification Name:	Plasma, Coagulation Control (per 21 CFR section 864.5425)
Equivalent Device:	Pacific Hemostasis Coagulation Control Plasma Level 1, 2 and 3 (#K984129, #K984130, #K984131, respectively)

Description of INR Control Plasmas

Pacific Hemostasis INR Control Plasmas is a set of five control plasmas with assigned INR values ranging from 1 to 5. All are lyophilized preparations of citrated plasma obtained from healthy donors. Stabilizers and buffers have been added prior to lyophilization. The plasma used to manufacture INR controls (1-5) is adjusted during the manufacturing process to yield the clot times with an INR ranging from 1 to 5. Each unit of source material used in the preparation of the reagent has been tested by a FDA approved method and found non-reactive for HBsAg and negative for antibodies to HIV and HCV.

Intended Use of INR Control Plasmas

Pacific Hemostasis® INR Controls, Levels 1 through 5, are intended for use as controls to check the performance of PT testing. Pacific Hemostasis INR Control Plasmas are a set of 5 control plasmas with assigned INR values ranging from 1 to 5. INR controls are designed to fall into the following ranges: 1-1.4 for INR #1, 1.5-2.0 for INR #2, 2.1-2.7 for INR #3, 2.8-3.5 for INR #4 and 3.6–5 for INR #5. Pacific Hemostasis warrants the INR values of Control Plasma only for use with Pacific Hemostasis-brand Thromboplastins.

Summary of Performance Data for Substantial Equivalence Comparisons

Between-run and within-run precision studies yielded equivalent data for INR Control Plasmas (1-5) and Coagulation Control Plasmas (Level 1 – 3). The average CV for each set of controls was less than 3% with a high of 10% and 11 % for the manual KC4 for the between-run and within-run precision studies testing.

Reconstituted stability studies performed at 2-8ºC also indicated equivalent performance with less than a 5% change at 8 hours. We conclude that the products are substantially equivalent.

Conclusion

Pacific Hemostasis INR controls and Coagulation Control plasma are prepared identically except the INR controls are adjusted to provide clot times that span the INR range from 1-5 while the coagulation controls are adjusted to discrete clot times that, after conversion to INR, span the INR range from 1 to 8. The following table illustrates where the INR Controls fall in relation to the Coagulation Controls.

Control	INR	PT*
Coagulation Level 1	~1	~11.5 sec
INR #1	~1.2	~12 sec
INR #2	~1.8	~15 sec
Coagulation Level 2	~2.5	~19 sec
INR #3	~2.5	~19 sec
INR #4	~3.0	~22 sec
INR #5	~4.5	~25 sec
Coagulation Level 3	~8	~34 sec

*Thromboplastin-D on a MLA-class instrument

The intended use of Coagulation controls is to monitor the performance of routine coagulation assays such as the PT, APTT and fibrinogen. The INR controls are intended specifically for the PT. INR controls are intended to substantiate the accuracy of INR testing and to validate the laboratory mean normal and International Sensitivity Index (ISI) used to calculate the INR from the PT. The performance data presented here and technological characteristics support the substantial equivalence claim for Pacific Hemostasis INR Controls set are substantially equivalent to Coagulation Control set consisting of Levels 1, 2, and 3. *Based on the data provided, it is our conclusion that these two products are substantially equivalent.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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SEP - 7 2001

Re: K010750
Trade Name: INR Control Plasmas
Regulation Number: 21 CFR § 864.5425
Regulatory Class: II
Product Code: GGN
Dated: July 23, 2001
Received: July 24, 2001

Dear Ms. Greenidge:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Pacific Hemostasis® INR Controls, Levels 1 through 5, are intended for use as controls to check the performance of PT testing. Pacific Hemostasis warrants the INR values of Control Plasma only for use with Pacific Hemostasis-brand Thromboplastins.

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K010750